K121777

JUL 18 2012

510(k) Summary of Safety and Effectiveness

Submitted by:	United Orthopedic Corporation
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Date of Summary:	June 15, 2012
Contact Person	Fang-Yuan Ho Regulation and Document Management
Proprietary Name:	U2 Acetabular Cup, Plasma Spray
Common Name:	Hip Prosthesis
Device Classification Name and Reference:	Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis per 21CFR 888.3358 This falls under the Orthopedics panel.
Device Class	Class II
Panel Code	Orthopaedics Device
Device Product Code:	LPH, MEH
Predicate Device:	1. "United" U2 Acetabular Component (K050262) 2. "ENCORE MEDICAL, L.P." FMP Acetabular Shell (K063257) 3. "Depuy" Pinnacle® Duofix® HA Shells (K031495) 4. "BIOMET®" Universal® Acetabular Component (K921301)

Device Description:

"UNITED" U2 Acetabular Cup - Plasma Spray is an extension of cleared "UNITED" U2 Acetabular Component (K050262). The materials, safety and effectiveness of this

subject are identical to the previously cleared U2 Acetabular Cup (K050262), except for adding sizes and multi-hole cup design. The extension of each coating type is described as following:

1. U2 Acetabular Cup – Ti Plasma Spray Coating: This submitted device adds the clustered-hole and multi-hole designs in sizes 44 ~ 80 mm and extends the size of no-hole design to #80. The catalog numbers of the cleared no-hole design are shifted to be used by clustered-hole, and the no-hole design is given new catalog numbers and extends its size to # 80. They are coated with CP Ti powder (ASTM F1580) to form a rough surface.
2. U2 Acetabular Cup -- HA/Ti plasma spray Coating: This submitted device extends cup size to #80 and increase the no-hole and multi-hole cup design for alternative. They are coated with dual coatings, which are CP Ti powder (ASTM F1580) for the inner layer and HA (ASTM F1185) for the outer layer.

This device is intended to be used with the previously cleared U2 Acetabular cup liner (K050262), U2 XPE liner (K111546), "UNITED" Femoral head (K994078, K022520), "United" Ceramic Femoral Head (K103497, K112463) and Titanium cancellous bone screw (K050262) in corresponding size. The modifications of Acetabular cup do not affect the intended use of the device or alter the fundamental scientific technology of the device.

Intended Use

The devise is used for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:

1. Non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia;
2. Inflammatory degenerative joint disease such as rheumatoid arthritis;

3. Correction of function deformity;
4. Revision procedures where other treatments or devices have failed; and
5. Treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement that is unmanageable using other techniques.

The devise is intended for uncemented use and is single use only.

This is the **same intended use** as previously cleared for **"UNITED" U2 Acetabular Component, K050262.**

Basis for Substantial Equivalence:

The safety and effectiveness of this device are substantially equivalent to previously cleared U2 Acetabular Component (K050262), except for an extension in size distribution and for an increase of multi-hole cup design. The modifications do not change the intended use or fundamental scientific technology. In addition, the subject device is also substantial equivalence to the Predicate–"ENCORE MEDICAL, L.P." FMP Acetabular Shell (K063257), "Depuy" Pinnacle® Duofix® HA Shells (K031495) and "BIOMET®" Universal® Acetabular Component (K921301).

Performance Data:

The mechanical properties of the modified surface have been evaluated to conform to FDA guidance: *"Class II Special Controls Guidance Document: Hip Joint Metal/Polymer Constrained Cemented or Uncemented Prosthesis; Guidance for Industry and FDA"*. And the locking strength test completed as part of the design assurance process, demonstrated that this device is safe and effective and is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

United Orthopedic Corporation
% Ms. Fang-Yuan Ho
Regulatory Affairs Manager
No. 57 Park Ave 2 Science Park
Hsinchu 300 Taiwan

JUL 18 2012

Re: K121777
Trade/Device Name: U2 Acetabular Cup, Plasma Spray
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: II
Product Code: LPH, MEH
Dated: June 15, 2012
Received: June 18, 2012

Dear Ms. Ho:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510 (k) Number (if known): K121777

Device Name: Acetabular Cup, Plasma Spray

Indications for Use:

The devise is used for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:

1. Non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia;
2. Inflammatory degenerative joint disease such as rheumatoid arthritis;
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The devise is intended for uncemented use and is single use only.

Prescription Use ___x___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K121777